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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,045

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Masashi Okamoto

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03/25/2009

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

P.O. BOX 2902

MINNEAPOLIS, MN 55402-0902

EXAMINER

SHAW, AMANDA MARIE

ART UNIT

PAPER NUMBER

1634

MAIL DATE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<p><b>Application No.</b> 10/522,045</p>	<p><b>Applicant(s)</b> OKAMOTO ET AL.</p>	
	<p><b>Examiner</b> AMANDA SHAW</p>	<p><b>Art Unit</b> 1634</p>	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 02 March 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Carla Myers/  
Primary Examiner, Art Unit 1634

Continuation of 11. does NOT place the application in condition for allowance because: Regarding the rejection made under 35 USC 112 2nd paragraph the Applicants argue that it is clear from the recited features that at the time the collecting solution is poured, the centrifugation tube includes the liquid phase part absorbed by the water absorbing particles and the microorganism or cell caught on the surface of the water absorbing resin particles. Therefore the Applicants submit that claim 1 is fully consistent and definite.

This argument has been fully considered but is not persuasive. In the instant case the claims recite the phrase "wherein the collecting solution is poured into the centrifugation tube without separating the liquid phase part absorbed by the water-absorbing resin particles from the water absorbing resin particles that have absorbed the liquid phase part". This recitation is confusing because it is unclear if there is actually a liquid phase in the centrifugation tube prior to adding the collection solution. The first step of the claims requires that the water absorbing resin particles absorb substantially all of the liquid phase therefore at the time the collection solution is added there would not be a liquid phase in the centrifugation tube.

Regarding the rejection made under 35 USC 103 the Applicants respectfully submit that the rejection is relying on the improper use of hindsight in the interpretation of the references. The Applicants further argue that Sato is directed to separating only viruses whereas Wardlaw is directed to separating formed constituents in general. They further state that Sato is specifically intended to utilize particular types of particles that isolate viruses from other components in a sample which may adversely affect amplification. As such the use of hydrogel particles in amounts that would absorb all of the liquid in the sample as taught by Wardlaw would in fact frustrate the purposes of Sato, as such use of the hydrogel particles would capture unwanted components that may adversely affect the amplification reaction of the viral gene. They further argue that nothing in Sato teaches that the particles are added in amounts that substantially absorb all of the liquid of the sample and that Sato is silent as to whether their hydrogel particles are even capable of absorbing water. They state that even if it was assumed that Sato's hydrogel particles are capable of absorbing water it is clear that more hydrogel particles would need to be added in order to absorb essentially all of the liquid of the sample and that Sato clearly notes that the addition of virus binding particles in too large a quantity is undesirable. The Applicants further state that Wardlaw teaches away from the use of centrifugation and filters.

These arguments have been fully considered but are not persuasive. The previous office action acknowledges that Sato does not teach a method wherein the water absorbing particles absorb substantially all of the liquid in the liquid phase of a sample, however a 103 rejection was made and a secondary reference (Wardlaw) was used to cure this deficiency. Wardlaw teaches a method wherein it was desirable to use enough hydrogel so that essentially all of the liquid in a sample is absorbed (para 0011). Thus Wardlaw clearly teaches what is missing from Sato. The fact that Sato is concerned with separating only viruses whereas Wardlaw is directed to separating formed constituents is irrelevant because Wardlaw is only being relied upon for teaching a method wherein hydrogels are used to absorb all of the liquid in a sample. The Applicants argue that the use of hydrogel particles in amounts that would absorb all of the liquid in the sample as taught by Wardlaw would in fact frustrate the purposes of Sato however the Applicants have not provided any evidence that the particles would adsorb unwanted components. Further it is noted for the record that it is a property of any hydrogel that it is superabsorbent therefore it is a property of the hydrogel particles of Sato that they are capable of absorbing water. Further Sato away from adding additional particles, Sato merely states that in situations where there are small amounts of virus the use of too many particles results in low separation. One of skill in the art at the time of the invention would have recognized that the number of particles required would depend on the absorbent properties of the hydrogel particles, the amount of liquid present in the sample, and the amount of virus suspected of being in the sample, based on this information one would be able to choose the appropriate number of particles to use. Further it is noted that the method of Wardlaw does not use a centrifuge or filter but again Wardlaw is only being relied upon for teaching hydrogels. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).